

**REMARKS**

This paper is being presented in response to an official action dated November 8, 2005, wherein claims 1-5, 11-30, 43-49, 54-73, and 76-78 were pending and not withdrawn.

By the foregoing amendment to the specification, the cross-reference to the issued patent number of the parent application has been revised.

Claims 29, 30, 44, 72, and 73 are currently amended. Support for the amendments is found in the specification claims as originally filed.

A check in the amount of \$120 is enclosed to cover the requisite fee under 37 C.F.R. § 1.17(a) for an extension of time for reply within the first month. The Commissioner is hereby authorized to charge any deficiency in connection with this Amendment, or any additional fees which may be required in connection with this Amendment, to Deposit Account No. 13-2855. A copy of this Amendment is enclosed.

Entry of the amendments to the specification, reconsideration of the rejected claims, and allowance of all pending claims are respectfully requested in view of the following remarks.

**Information Disclosure**

The International Search Reports submitted on the IDS filed on June 13, 2005 have not been considered. The official action alleges that the references “are not appropriate for IDS.” See ¶ 4 of the action.

It is respectfully submitted that the references are appropriate under 37 C.F.R. § 1.98 as a “publication” or “other information,” and that the references may potentially be considered material under 37 C.F.R. § 1.56(b) as “inconsistent with, a position the applicant takes in: (i) Opposing an argument of unpatentability relied on by the Office, or (ii) Asserting an argument of patentability.” For example, while the applicants assert that the claims are patentable over the references, some references have inconsistently been categorized by the ISRs as “particularly relevant if combined with another document of the same category.” See also MPEP 2001.04 (materiality is not limited to prior art; information is intended to be all-encompassing)

It is respectfully submitted that the information submitted should be considered by the Patent Office. If the objection to the references is maintained, then the Patent Office must provide authority therefor in the patent statute or rules.

**The 35 U.S.C. § 112, ¶ 2, Rejections are Moot or Traversed**

Claims 29, 30, 44-49, 54-73, and 76-78 have been rejected under 35 U.S.C. § 112, ¶ 2, as being indefinite. See ¶6 of the action. In view of the following comments, reconsideration and withdrawal of the rejections are respectfully requested.

Claims 29, 30, 72, and 73 were rejected on the basis that “HLB . . . needs to be defined.” It is respectfully submitted that a person of ordinary skill in the art would understand this claim term in view of the specification of the patent (see, for example, page 11, lines 8-9; see also granted claims 29 and 30 of U.S. Patent No. 6,656,470, issued from the parent application). Nevertheless, in an effort to advance the application to allowance, amendments are proposed for the claims, whereby “hydrophile/lipophile balance” is recited in place of HLB. The scope of the claim is unchanged. However, if upon reconsideration the examiner agrees with the foregoing argument, then it is respectfully requested that the amendments to claims 29, 30, 72, and 73 be refused entry.

Claim 44 was rejected on the basis that the phrase “said cations” has insufficient antecedent basis. It is respectfully submitted that antecedent basis is inherent in the recitation of “multi-cation cross-linked alginate.” See MPEP 2173.05(e) (“Inherent components of elements recited have antecedent basis in the recitation of the components themselves. For example, the limitation ‘the outer surface of said sphere’ would not require an antecedent recitation that the sphere has an outer surface.”) Nevertheless, in an effort to advance the application to allowance, an amendment is proposed for the claim, whereby “the cations of said multi-cation crosslinked alginate” is recited in place of “said cations.” The scope of the claim is unchanged. However, if upon reconsideration the examiner agrees with the foregoing argument, then it is respectfully requested that the amendment to claim 44 be refused entry.

Claim 44 was also rejected on the basis that the phrase “a composition” “needs to be differentiated.” It is unclear which recitation of the phrase is rejected. Nevertheless, it is respectfully submitted that both recitations are clear on the face of the claim. The first recitation is obviously the vaccine composition, and the second recitation relates to the alternative expression of the cellulose ether and surfactants. To remove any alleged doubt,

and advance the application to allowance, an amendment using a different alternative expression is proposed for the claim, whereby “one or both of a cellulose ether and a poly(ethylene oxide)-poly(propylene oxide)-poly(ethylene oxide) triblock copolymer surfactant” is recited in place of “a composition selected from the group consisting of a cellulose ether, a poly(ethylene oxide)-poly(propylene oxide)-poly(ethylene oxide) triblock copolymer surfactant, and combinations thereof.” The scope of the claim is unchanged. However, if upon reconsideration the examiner agrees with the foregoing argument, then it is respectfully requested that the amendment to claim 44 be refused entry.

### **The 35 U.S.C. § 103(a) Rejection is Traversed**

Claims 1-5, 14-28, 43-49, 57-71, 77, and 78 have been rejected under 35 U.S.C. § 103(a) as being obvious over the combination of U.S. Patent No. 5,674,495 in view of the Jackson Thesis and U.S. Patent No. 4,792,452. See ¶ 8 of the action.

Claims 1, 2, 4, 11-19, 21-30, 43, 44, 54-62, 64, 71-73, 76, and 78 have been rejected under 35 U.S.C. § 103(a) as being obvious over the combination of U.S. Patent No. 5,674,495 in view of the Jackson Thesis and U.S. Patent No. 5,019,100. See ¶ 9 of the action.

### ***Proper Basis for a § 103(a) Rejection***

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the teachings of a plurality of references. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all of the claim limitations.

It is “incumbent upon the examiner to identify wherein each and every facet of the claimed invention is disclosed in the applied reference.” *Ex parte Levy*, 17 USPQ2d 1461, 1462 (Bd. Pat. App. & Inter. 1990) (citing *Lindemann Maschinenfabrik GmbH v. American Hoist and Derrick*, 221 USPQ 481, 485 (Fed. Cir. 1984)).

### **No Prima Facie Case of Obviousness Has Been Made and, therefore, the § 103(a) Rejections are Traversed**

The '495 patent, Jackson Thesis, and '452 patent do not teach or suggest all of the elements recited in the claims. Thus, no prima facie case of obviousness has been made

in the instant action, and none exists based on the combination of the applied references. Accordingly, reconsideration and withdrawal of the § 103(a) rejections are respectfully requested.

In particular, the '495 patent teaches only the use of calcium chloride. In contrast, the claimed method (e.g., claim 1) recites "crosslinking the alginate in the emulsion of step (A) with at least two cations." There is no teaching or suggestion in the prior art to perform the claimed method with such a step.

Given this shortcoming, it is respectfully submitted that the claimed invention is unobvious. Accordingly, reconsideration and withdrawal of the rejections are requested.

The official action points out that "the patentability of a product does not depend on its method of production." See page 4, second paragraph, and page 5, third paragraph. The significance of this statement is not apparent, as the present claims are method claims, not product claims. If the rejections are maintained, then clarification is requested.

#### CONCLUSION

In view of the foregoing amendments and remarks, withdrawal of the rejected claims, rejoinder of the withdrawn claims, and allowance of all pending claims 1-34 and 43-78 are respectfully requested.


Should the examiner wish to discuss the foregoing, or any matter of form or procedure in an effort to advance this application to allowance, the examiner is urged to telephone the undersigned attorney at the indicated number.

Respectfully submitted,

MARSHALL, GERSTEIN & BORUN LLP

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By

  
Michael Muczynski (Reg. No. 48,642)  
Attorney for Applicants  
6300 Sears Tower  
233 South Wacker Drive  
Chicago, Illinois 60606-6357  
Phone: (312) 474-6300  
Fax: (312) 474-0448